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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John W. SHULTZ, *et al.*

Serial No.: 09/924,981

Filed: August 7, 2001

For: PYROPHOSPHOROLYSIS AND INCORPORATION OF NUCLEOTIDE METHOD FOR NUCLEIC ACID DETECTION

Examiner: Not Yet Assigned

)
) Attorney Docket:
) 6868/82379
) PRO-107.2
)
) Art Group: 1655

INFORMATION DISCLOSURE STATEMENT

Commissioner For Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.97, a list of documents that may be material to the examination of this application is provided on the attached Form PTO-1449. Listed Documents A1-A20, B1-B24, C1-C60, D1, E1-E11, F1-F34, G1-G3, G5, H1-H2, J1-J27 and K1 are U.S. or foreign patents or pertinent articles that may be relevant to the examination of the present application. Listed Documents A1-A20, B1-B24, C1-C60, D1, E1-E11, and F1-F34 have already been provided to the U.S. Patent Office during prosecution of parental cases. Pursuant to 37 C.F.R. 1.98(d), it is understood that only a list of art is required inasmuch as the art has been provided and discussed previously. However, copies of any of the listed documents will be provided upon the request of the Examiner. Copies of documents D1, G1-G3, G5, H1-H2, J1-J27 and K1 are provided herewith.

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Documents A1-A20, B1-B24 and E1-E11, listed on the attached Form PTO-1449, were cited and supplied to the Patent and Trademark Office in the parental application, Serial No. 09/042,287, filed March 13, 1998, the benefit of which filing date is claimed herein.

Documents C1-C60 and F1-F34, listed on the attached Form PTO-1449, were cited and supplied to the Patent and Trademark Office in the parental application, Serial No. 09/358,972, filed July 21, 1999, the benefit of which filing date is claimed herein.

Document D1, listed on the attached Form PTO-1449, was cited and supplied to the Patent and Trademark Office in the parental application, Serial No. 09/242,436, filed February 18, 1999, the benefit of which filing date is claimed herein. A copy of document D1 is enclosed herewith.

Document G1 listed on the attached Form PTO-1449 was cited and supplied to the Patent and Trademark Office in the parental application, U.S. Serial No. 09/358,972, filed March 13, 1998. A copy of document G1 is provided herewith.

Document G2 was brought to our attention by the U.S. Patent Examiner during prosecution of U.S. Serial No. 09/790,417 filed February 2, 2001, a continuation of U.S. Serial No. 09/398,972 filed July 21, 1999 for which the benefit of priority is claimed on the disclosures incorporated by reference, now U.S. Patent No. 6,235,480 B1 issued May 22, 2001. A copy of document G2 is provided herewith.

Document G3 discloses oligodeoxynucleotides modified at the 3'-terminal phosphodiester internucleotide linkage so that they are resistant to nuclease digestion. Such modified oligos are disclosed as useful in decreasing gene expression where RNaseH cleaves

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mRNA in a DNA:RNA hybrid with the modified nucleotide. A copy of document G3 is provided herewith.

Document G5 is incorporated as background related to the invention. Document G5 (*Kajiyama, et al.*) discloses thermostable luciferase of firefly, thermostable luciferase gene of firefly, novel recombinant DNA and process for the preparation of thermostable luciferase of firefly. A copy of document G5 is provided herewith.

Document H1 listed on the attached Form PTO-1449 is the published PCT application corresponding to U.S. Serial No. 09/252,436 filed February 18, 1999, now U.S. Patent No. 6,159,693 issued Dec. 12, 2000, for which the benefit of priority is claimed and disclosures thereof incorporated by reference. A copy of the first page of document H1 is provided herewith.

Document H2 listed on the attached Form PTO-1449 discloses length determination of nucleic acid repeat sequences by discontinuous primer extension. A copy of document H2 is provided herewith.

Document J1 listed on the attached Form PTO-1449 is the published PCT application corresponding to U.S. Serial No. 09/383,316 filed August 25, 1999, for which the benefit of priority is claimed and disclosures thereof incorporated by reference.

Document J2 listed on the attached Form PTO-1449 is the published PCT application of U.S. Serial No. 09/252,436 filed February 18, 1999, for which the benefit of priority is claimed and disclosures thereof incorporated by reference.

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Document J3 listed on the attached Form PTO-1449 is the published PCT application corresponding to U.S. Serial No. 09/406,147 filed September 27, 1999, which is a continuation-in-part of 09/358,972 filed July 21, 1999 for which the benefit of priority is claimed and disclosures thereof incorporated by reference.

Document J4 listed on the attached Form PTO-1449 is the published PCT application of U.S. Serial No. 09/425,460 filed October 22, 1999, which is a continuation-in-part of 09/358,972 filed July 21, 1999 for which the benefit of priority is claimed and disclosures thereof incorporated by reference.

Documents J5-J27 are documents that have not been provided to the U.S. Patent Office in any of the earlier-filed, related cases. Documents J5-J13 are enclosed herewith, and documents J14-J27 will be provided after the undersigned obtains copies, but are discussed hereinunder.

Documents J5-J10 are articles relating to repeating sequences, *Alu*, or other interspersed repeating mammalian nucleic acid sequences. Document J11 is an article disclosing a mechanism of DNA Polymerase I: Exonuclease/Polymerase Activity Switch and DNA Sequence Dependence of Pyrophosphorolysis and Misincorporation Reactions. Document J12 is an article disclosing a Structure and Assembly of the *Alu* Domain of the Mammalian Signal Recognition Particle. Document J13 is an article disclosing a Common 82-Nucleotide Sequence Unique to Brain RNA. Document J14 discloses a Method and Reagent for Bioluminescence. Document J15 discloses a Method for Blocking the Expression of Specifically Targeted Genes.

Document J16 discloses Length Determination of Nucleic and Repeat Sequences of Discontinuous Primer Extension.

Documents J14-J21 are background articles providing examples of diseases involving gene-level defects, and will be provided under separate cover at a later date.

Documents J14-J21 are discussed in the specification of the present application. In the present application, we teach that the present invention is useful for providing sensitive, reliable assays with diagnostic and preventative applications in human and animal health care for such diseases associated with gene-level defects. Document J14, Van Essen et al. *J. Med. Genet.* **34**:805-12 (1997) discloses a study of the dystrophin gene in Duchenne and Becker muscular dystrophy patients as detected by Southern blotting or multiplex PCR. Document J15, Calvano et al. *Clin. Genet.* **52**:17-22 (1997) discloses the use of PCR fragments used as fluorescent probes for the detection of female carriers of Duchenne and Becker muscular dystrophy. Document J16, Jongpiputvanich et al. *J. Med. Assoc. Thai.* **79 (Supp. 1)**:S15-21 (1996) discloses the use of multiplex PCR and microsatellite or STR analysis for diagnosis and carrier detection in a Duchenne muscular dystrophy family. Document J17, Pastore et al. *Mol. Cell. Probes* **10**:129-37 (1996) discloses a quantitative PCR analysis method using radiolabeled PCR products for the detection of macrodeletion carriers of Duchenne and Becker muscular dystrophy. Document J18, Katayama et al. *Fetal Diagn. Ther.* **9**:379-84 (1994) discloses a study of the efficacy of PCR for prenatal diagnosis of Duchenne muscular dystrophy using PCR-restriction fragment length polymorphism analysis, multiplex PCR, and dinucleotide repeat polymorphism analysis to diagnose affected male fetuses and detect carrier female fetuses in the first trimester. Document

J19, Shohet et al. *Arterioscler. Thromb. Vasc. Biol.* **19**:1975-78 (1999) discloses a study of the frequency of the -514T allele of hepatic lipase in white men with coronary artery disease.

Document J20, Boerma et al. *Intern. Med.* **246**:211-218 (1999) discloses a polymorphism in the human gap junctional protein connexin 37 as a prognostic marker for atherosclerosis. Document J21, Sugiyama et al. *Mutat.* **14**:90 (1999) discloses the detection of a novel missense mutation in the presenilin-1 gene in a family with presenile familial Alzheimer's disease (FAD). These workers report that over 50 such missense mutations in the presenilin-1 gene have been reported in families with FAD.

Documents J22-J27 are background articles providing examples of known methods for detecting the size of a nucleic acid probe that are useful as a step or steps in some embodiments of the present invention, and will be provided under separate cover at a later date. Documents J22-J27 are discussed in the specification of the present application. Document J22, Wei, J. et al. *Nature*. **399**:243-246, 1999 discloses a method for analyzing the size of a labeled nucleic acid probe by silicon desorption ionization mass spectroscopy. Document J23, Niessen W. J. *Chromatog. A* **794**:407-435 (1998) discloses other liquid chromatography-mass spectrometry (LC-MS) instrumentation that is useful for analysis of a labeled nucleic acid probe. Documents J24-J25, Jain, et al. *Biochem. Biophys. Res. Commun.* **200**:1239-1244 (1994) and Levitt, B. et al. *Anal. Biochem.* **137**:93-100 (1984) disclose analysis of a denatured labeled nucleic acid probe strand in the solution by HPLC using a fluorescence detector. Documents J26-J27, Revich et al., *J. Chromatography*, **317**:283-300 (1984), and Perrone & Brown, *J. Chromatography*, **317**:301-310 (1984) provide examples of the HPLC separation of dNTPs.

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Document K1, Caskey et al., U.S. Patent No. 5,582,989, is a background multiplex PCR method disclosing a multiplex genomic DNA amplification for deletion detection.

Documents for which the supplied date of publication lists the year of publication without the month were published sufficiently earlier than the effective U.S. filing date and any foreign priority date, so that the particular month of publication is not in issue. Pursuant to §609 of the MPEP, it is understood that the month of publication is not required when the particular month of publication is not in issue. Where no date is supplied, it is believed that the date of publication is not in issue.

No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material disclosed is equivalent to the subject invention. In addition, none of the documents that have publication dates prior to the priority date of the above application anticipate the invention in this application.

The cited documents disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the documents and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that the art or document

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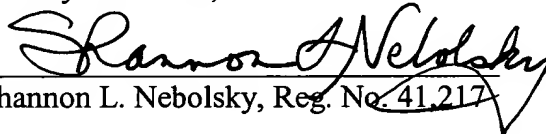
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disclosure is otherwise necessarily prior art as defined by the patent law with respect to the instant invention and application.

Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the art and documents recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application. The recitation herein of the art and documents is not to be construed as an assertion that more pertinent art could not possibly be in existence.

No fee or petition is believed to be necessary. However, should any fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

Respectfully submitted,

By 
Shannon L. Nebolsky, Reg. No. 41,217

Enclosures:

Form PTO-1449
Two Bound Volumes of Art D1, G1-G3, G5, H1-H2, F28, J1-J27 and K1
Return Mailing Postcard

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CERTIFICATE OF EXPRESS MAILING

I hereby certify that this Information Disclosure Statement, together with the stated enclosures, is being deposited with the United States Postal Service with Express Mailing Label No. EV 045 460 395 US in an envelope addressed to: Commissioner for Patents, Washington D.C. 20231 on November 6, 2002.

